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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,894	02/26/2002	Andrew P. Klock	12557-003001	2775

26161 7590 08/12/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,894

Applicant(s)

KLOEK ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6 and 8-10 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: allowable subject matter indicated.

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The Response to Restriction Requirement filed on July 21 as paper No. 10 is acknowledged. Applicants elected Group II, claims 5-10, without traverse. Claims 1-18 are pending in the application. Claims 2-10 are the subject of this Office Action. Claims 1-4 and 11-18 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions.

DETAILED ACTION

1. Objections

1.1. Specification

The disclosure is objected to because SEQ ID NO: 3 is referred to by Applicants throughout the specification; see for example page 9, line 17, page 28 line 8, figure descriptions on page 15 and other numerous places in the text, as the polynucleotide sequence. According to the Paper Sequence Listing SEQ ID NO:3 is an amino acid sequence.

The typographical error on page 16, line 1 "mutates" should be corrected.

On page 18, line 20, GenBank number is missing.

The disclosure is objected to because it contains on page 21, line 30, an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

1.2. Claims

Claim 4 is objected to because the claim is depending on claim 4 that does not belong to the elected invention.

2. Rejections

2.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is confusing, because it is directed to the nucleotide sequence of SEQ ID NO: 3, however SEQ ID NO: 3 is disclosed in the paper copy of the sequence listing as an amino acid sequence.

2.2. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2.1.1. Lack of written description

Claims 5, 6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a large and variable genus of polynucleotide sequences that encode polypeptides comprising amino acid sequences being at least 80% identical to SEQ ID NO: 2. However, the function of the genus is not stated by the claim. The specification discloses only a single representative of the claimed genus, which is the polynucleotide of SEQ ID NO: 1 encoding the phosphoglycerate mutase of *Meloidogyne incognita* of SEQ ID NO: 2. This is, however, insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Applicants fail to disclose any particular structure to function/activity relationship for polynucleotide set forth by SEQ ID NO: 1. No information, beyond the characterization of SEQ ID NO: 1 as encoding the phosphoglycerate mutase activity,

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has been provided by Applicants. This characterization is not indicative that they had possession of the claimed genus of the polynucleotides encoding an amino acid sequence that is at least 80% identical to the amino acid sequence of SEQ ID NO: 2 and having the desired biological activity. It is well known in the art that a change of one nucleotide in encoding sequence can render the protein inactive. Applicants do not teach how to modify SEQ ID NO: 1 so that it encoded a polypeptide comprising an amino acid sequence that is at least 80% identical to the amino acid sequence of SEQ ID NO: 2, wherein said polypeptide retains the desired biological activity.

Given the lack of functional characteristics of the genus of DNA molecules encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention when the application was filed.

2.2.2. Scope of enablement

Claims 5, 6, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 encoding SEQ ID NO: 2, the phosphoglycerate mutase of *Meloidogyne incognita*, a nematode species, does not reasonably provide enablement for an isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 80 % identical to the amino acid sequence of SEQ ID NO: 2. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the claims covers a large and variable genus of DNA molecules with structural similarity to SEQ ID NO: 1, for which the guidance in the specification is clearly lacking.

Factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompass an extremely the large genus of DNA molecules for which the structure/function relationship is not identified and therefore experimentation aimed at construction of DNA encoding polypeptides comprising a polypeptide having at least 80% identity to SEQ ID NO: 2 and still encoding the desired activity, has a low probability of success. Applicants did not provide any example or guidance how to construct the claimed DNA molecules. Therefore, to make the invention one skill in the art had to determine the region of SEQ ID NO: 1 that encodes the desired activity of phosphoglycerate mutase. While enablement is not precluded by the necessity for routine experimentation, if a large amount DNA construct screening is required, the specification must provide a

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reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality of encoding the phosphoglycerate mutase activity. The provision of SEQ ID NO: 1 fails to provide such guidance of polynucleotides with structural variations therefrom which remain encompassed within the scope of the rejected claims.

Without a further guidance on the part of Applicants regarding specific modification of the DNA SEQ ID NO: 1 so that that the claimed species have the functionality of encoding the phosphoglycerate mutase activity, making the claimed invention is well outside the realm of a routine experimentation and therefore is undue.

3. Conclusion

Although no claim is in condition for allowance the claims contain allowable subject matter. Claim 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim.

The following is the examiner reason for allowable subject matter. Applicants disclose a unique SEQ ID NO: 1 encoding phosphoglycerate mutase of *Meloidogyne incognita*, a nematode species. No prior art anticipates or fairly suggests the invention. Phosphoglycerate mutase is an enzyme fundamental in glycolysis and gluconeogenesis, thus it is an attractive target for the development of compounds toxic to nematodes, parasites of plants and animals, including *Homo sapiens*.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

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PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600